

DETAILED ACTION

Claims 91, 92, 94, 95, 97, 98, 101 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 98 remains under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Other rejections under 35 U.S.C. 112, second paragraph, not repeated here is withdrawn or moot in view of cancelled claims.

Applicant argues that in order to expedite claims have been cancelled and amended.

The amendment and applicant's argument have been fully considered but found unpersuasive because the base claim 91 now has two active ingredients (LY294002 and Wortmannin). The specification at Fig. 12, for example, discloses over-expression of "PTEN in COS7 cells inhibits ITAM signaling". This disclosure suggests that the function recited in claims 98 is the inherent function of two active ingredients in claim 91. Reciting the same active ingredients in a dependent claim does not further limit the base claim it depends on.

The rejection of claims under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of the amendment.

Claim Rejections - 35 USC § 102

Claims 91, 92, 94, 95, 97, and 98 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. 6,632,789 (the '789 patent hereinafter, filing date of 4/1994).

Applicant argues that claim 91 is amended to recite a positive step of assessing immunoreceptor signaling following administration of the PI-3 kinase inhibitor.

Applicant states the support for the amendment is found on page 4 lines 31-34:

PTEN has also been implicated in immunoreceptor modulation. Thus, in yet another aspect of the invention, methods for inhibiting the immune response in target cells are provided. PTEN agonists, PI3 kinase inhibitors and/or AKT inhibitors are administered to patients to prevent or inhibit immunoreceptor signaling. Such agents should have efficacy in the treatment of graft rejection or graft



The specification on page 4 lines 29-35 reasonably communicates that assessing immunoreceptor signaling following administration of the PI-3 kinase inhibitor means monitoring efficacy of treatment of graft rejection. Since the '789 patent teaches (note claims 1 and 16) a method of administering LY294002 or Wortmannin and also teach (note claims 2-4 and 17-19) that the monitoring ("response") of effectiveness of the administered LY29002 or Wortmannin is to determine T cell proliferation and production of at least one lymphokine and interleukin-2, the '789 patent anticipates the amended claims.

The rejection of claims under 35 U.S.C. **102(b)** as being anticipated by Schultz et al Anticancer Res. 1995 Jul-Aug;15(4):1135-9 is withdrawn, because the amended

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claims are no longer anticipated. However, Schultz et al., Anticancer Res. 1995 Jul-Aug;15(4):1135-9 is used in the obviousness rejection below.

Double Patenting, Withdrawn

Upon review and reconsideration, the ODP of record is withdrawn because applicant's statement that the instant application is due to restriction requirement is persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 101 is rejected under 35 U.S.C. 103(a) as being unpatentable over the '789 patent of record as applied to claim 91 above, and further in view of Schultz et al of record.

Claim 101 recites three common administration route of the active ingredient in base claim 91.

The '789 patent teaches the active ingredient for the same purpose stated in the preamble of the instant claim 91 (see above and previous Office action for further details).

However, the '789 patent does not specifically teach the three routes of administration recited in the instant claim 101.

However, Schultz et al of record teach that the administration of oral administration of Wortmannin had been well known in the art.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing the instant application with a reasonable expectation of success.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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